

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO:</b>  <i>Wave 2 Cases</i>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE  
GENERAL OPINION TESTIMONY OF LARRY T. SIRLS, II, M.D.**

**I. PRELIMINARY STATEMENT**

Now come Plaintiffs seeking to exclude, or to limit in the Court's discretion, the expert testimony of Dr. Larry T. Sirls, II, M.D. ("Dr. Sirls"), pursuant to Federal Rule of Evidence ("Rule") 702 and the standards set forth by the United States Supreme Court in *Daubert v. Merrell Dow Pharms. Inc.* 509 U.S. 579 (1993) and as adopted by the Fourth Circuit. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(federal law governs the admissibility of expert testimony). Dr. Sirls seeks to offer general opinions regarding the TVT ("TVT") and the TVT-O ("TVT-O") slings, manufactured and marketed by Defendant Ethicon, Inc. ("Ethicon"), for the treatment of stress urinary incontinence ("SUI"). His opinions are proffered in the Expert Report of [Dr. Sirls] ("Sirls Report")<sup>1</sup> and in his deposition testimony of July 21, 2016.<sup>2</sup> Plaintiffs now

<sup>1</sup> The Sirls Report is attached hereto as Exhibit A. Citations to the Sirls Report are in the form (Ex. A, \_\_\_\_).

<sup>2</sup> Relevant excerpts of Dr. Sirls's deposition of July 21, 2016 are attached hereto as Exhibit B. Citations to it will be in the form (Ex. B, \_\_\_\_; \_\_\_\_; \_\_\_\_).

seek to exclude or limit Dr. Sirs's opinions regarding the TVT and the TVT-O as set forth herein because:

- he is not qualified to proffer opinions regarding the biochemical make-up or other material aspects of the TVT or TVT-O devices and is likewise unqualified to proffer expert opinions regarding any regulatory documents and/or the legal adequacy of the warnings in the instructions for use ("IFU") accompanying the TVT or the TVT-O;
- his opinions supported by internal Ethicon documents must be excluded because they constitute inadmissible evidence regarding Ethicon's thought processes in developing and marketing the TVT and the TVT-O; and
- his opinions based on data or his clinical experience regarding devices other than the TVT or the TVT-O are outside the scope of his opinion here.

In addition, Dr. Sirs testified on the record as follows and his opinions must be limited at trial to reflect that:

- he has done no independent research on whether the polypropylene mesh in the TVT or TVT-O degrades and has no basis in his clinical practice to support such opinions;
- outside of his review of "internal documents," opinions about which should be excluded generally, Dr. Sirs lacks any reliable basis to offer opinions about the differences between laser-cut and mechanical-cut mesh devices;
- TVT and TVT-O devices can both rope, curl, and otherwise change shape if subject to improper tension;
- mesh extrusion, exposure, and erosion into the vagina and other structures is unique to mesh; and
- in his practice, he has treated women with mesh implants who suffered recurrent or continued SUI, mesh exposure or erosion into the vagina, urethra and/or bladder; and has treated women who had to have their slings removed at least partially.

## II. LEGAL STANDARD

Rule 702 states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702.

The Supreme Court in *Daubert* assigned to district courts a “gatekeeping function” in determining whether expert testimony is both reliable and relevant and, thus admissible, under Rule 702. 509 U.S. 579. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152; *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)(“Under [Rule] 702, trial judges act as gatekeepers to ensure that any and all scientific testimony . . . is not only relevant, but reliable,”) (internal citations and quotations omitted.). Under both *Daubert*, 509 U.S. 579, and Rule 104(a) - the statute imposing a duty on courts to decide preliminary questions regarding the qualifications of witnesses and/or the admissibility of evidence -- this Court must determine whether the requirements of Rule 702 are met before any expert testimony can be presented to the jury. *See, Cooper*, 259 F.3d at 199; (the district court determines whether the methodology employed by the expert is “scientifically valid” and whether that methodology is applicable to the facts in issue). While *Daubert* requires Rule 702 to be applied flexibly, unfettered admissibility is not the standard and “the proponent of the testimony must establish its admissibility by a preponderance of proof.” *See Cooper*, 259 F.3d at 199 (citing to *Daubert*, 509 U.S. at 592 n. 10; *see also Hines v. Wyeth, C. A. No. 2:04-0690*, 2011 WL 2792436 at \*2 (S.D.W.Va. July 14, 2011).).

### **III. LEGAL ARGUMENT**

#### **A. DR. SIRLS'S GENERAL OPINIONS MUST BE LIMITED TO THE SCOPE OF HIS EXPERT REPORT AND HIS DEPOSITION TESTIMONY**

As this Court has previously held, an expert should not be allowed to testify “outside the scope of [his] expert opinion.” *See Huskey v. Ethicon*, C. A. No. 2:12-cv-05201, 2014 WL 3861778 at \*5 (S.D.W. Va. August 6, 2014). Dr. Sirls’s general report is clearly limited in scope to opinions regarding two products manufactured and marketed by Ethicon: the TVT and the TVT-O. (See Ex. A.)

Nevertheless, Dr. Sirls grounded many of his opinions regarding the TVT-O in his clinical experience with Ethicon’s Abbrevo device. (Ex. A, 3.)(See Ex. B, 55:8-64:1.) But even he admitted that the Abbrevo differs from the TVT-O, (Ex. B, 55:10-13) stated that it [i.e. the Abbrevo] was his “sling of choice now for many, many, reasons,” (*id.*, 55:19-20) and that he no longer routinely used the TVT-O. (*Id.*, 59:6-9.) Further, Dr. Sirls testified that he preferred the shorter length of mesh in the Abbrevo, precisely because of its potential to reduce some complications, (*id.*, 57:21-59:2) thereby reinforcing that he well understood that the TVT-O and the Abbrevo were different slings. To the extent that Dr. Sirls grounded his opinions regarding the TVT-O on either his research concerning or on his clinical experience with the Abbrevo, such opinions must be dismissed.

#### **B. DR. SIRLS IS NOT QUALIFIED TO OFFER SEVERAL OF THE OPINIONS IN THE SIRLS REPORT**

##### **1. Dr. Sirls Is Not Qualified To Proffer The Opinion That The IFUs Accompanying The TVT And The TVT-O Are Legally-Adequate.**

Dr. Sirls is an urologist who completed a fellowship in female urology and urodynamics.<sup>3</sup>

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<sup>3</sup> See Curriculum Vitae (“CV”) of [Dr. Sirls] attached hereto as Exhibit C at 1. Future citations to Exhibit C will be in the form (Ex. C, \_\_\_\_).

He lacks special qualifications in law or regulatory matters. (*Id.*) As this Court has previously held, medical experts are not qualified to offer opinions regarding the adequacy of a corporate defendant's IFU that accompanies a mesh device when marketed, based only on their own experience. *See Sederholm v. Boston Scientific Corp.*, C. A. No. 2:13-cv-12510, 2016 WL 3282587 at \*13 (S.D.W. Va. June 14, 2016)(excluding urologist's expert opinions on the adequacy of defendant's IFU that he based solely on the risks he observed in his practice.). Dr. Sirls offers just such opinions in the Sirls Report (Ex. A, 82-83) and at his deposition, stating 1) that an IFU merely needs to provide warnings that are "unique" to the device it accompanies; (see e.g., Ex. B, 52:17-22) 2) that the IFU Ethicon provided regarding the TVT prior to 2015 was adequate inasmuch as it was "intended to augment the physician's knowledge base;" (*id.*, 77:23) 3) that the pre-2015 IFU sufficed because it was personally adequate for him (*id.*, 78:13) and generally adequate for all; (*id.*, 79:2-7) and 4) that the 2015 IFU TVT-O was adequate because it was the same as the previous one. (*Id.*, 79:16-20.)<sup>4</sup>

In addition, Plaintiffs move to exclude Dr. Sirls's opinions regarding regulatory matters including opinions issued by the Food and Drug Administration (Ex. A, 3, 76-79, 84) because he is not qualified to proffer them. (See Ex. B, 91:1-4)(testifying to his "understanding" that per federal regulations and guidelines IFUs only need to include aspects of devices that are "unique.")). As this Court has held, medical experts may not proffer opinions based upon their understanding of FDA regulations because such constitutes a legal conclusion and not an expert opinion. *See e.g., Tyree v. Boston Scientific Corp.*, 54 F.Supp.3d 501, 543 (S.D.W. Va. 2014.).

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<sup>4</sup> On cross examination, Dr. Sirls acknowledged one small difference in the two IFUs concerning transient leg pain. (*Id.*, 131:8-24.) However, he did not step back from his opinion that the 2015 IFU is adequate because the pre-2015 was. In any event, Plaintiffs hereby move to exclude Dr. Sirls's opinions on the adequacy of IFUs because he is unqualified to make them.

**2. Dr. Sirls Is Not Qualified To Proffer Opinions About The Biomaterials Or The Biomechanics Of The TVT And TVT-O Devices.**

As said, Dr. Sirls is an urologist. (Ex. C, 1.) He is not a bioengineer and has no special training that qualifies him to offer opinions about the biochemical, bioengineering, or biomechanical aspects of the TVT-O and TVT devices. (Ex. A, 2-3, 17-18, 22-23, 29.) That Dr. Sirls is unqualified to proffer these opinions was made readily apparent on the record when he testified that he did not understand questions regarding the different “grades” of polypropylene; (Ex. B, 32:5-15) that he did not know what quantity of antioxidants were needed to turn prolene into polypropylene; (*id.*, 33:17-20) likewise did not know whether all mid-urethral slings on the market were made with the same base polypropylene; (*id.*, 34:8-11) had no understanding of additional additives other than two antioxidants; (*id.*, 37:23-38:11) and did not know the necessary concentration of antioxidants that needed to be added. (*Id.*, 39:2-5.) In short, Dr. Sirls, himself, had to admit, “I don’t specialize in polymers and plastics.” (*Id.*, 33:6.) Thus, notwithstanding his apparent belief that he qualifies as a biomaterials expert here, (see e.g. 29:6-14)(see also Ex. A, 2-3, 17-18, 22-23, 29) he does not and, consequently, may not proffer opinions regarding the biochemical make-up or any biomechanical or bioengineering aspects of the TVT and TVT-O slings. His opinions on these matters must be excluded in full. *See* Rule 702.

**C. DR. SIRLS’S OPINIONS GROUNDED IN ETHICON’S INTERNAL DOCUMENTS MUST BE EXCLUDED**

This Court has previously held that a medical expert cannot proffer testimony grounded in the internal documents of a corporate defendant if such evidence pertains to the “[defendant’s] knowledge, state of mind, or other matters related to corporate conduct and ethics,” holding that such will not assist the jury. *See In re Ethicon, Inc., Pelvic Repair System Products Liability Litig.*, No. 2:12-cv-4301, 2014 WL 186872 at \*6 (S.D.W. Va. January 15, 2014). Dr. Sirls, here, relies

on just this type of evidence to support some of his opinions and they must be excluded in full. (See Ex. B, 115:7-116:18)(Doctor Sirls admitting on the record that Ethicon's counsel chose the internal records that he reviewed, that he provided no parameters to counsel to guide what he was provided, and that in providing the documents "*they [Ethicon] were trying to help me understand the thought process that Ethicon was going through when they were looking at the issues that we're discussing.*") (quoted material at 115:23-116:2.) (emphasis added.). Any and all opinions Dr. Sirls grounds in these Ethicon internal documents must be excluded.

**D. SOME OF DR. SIRLS'S OPINIONS WERE LIMITED BY HIS DEPOSITION TESTIMONY AND SHOULD REMAIN SO AT TRIAL**

Dr. Sirls testified on the record as follows:

- that he has done no independent research on whether the polypropylene mesh in the TVT or TVT-O degrades and has no basis in his clinical practice to support such opinions; (*id.*, 40:8-21)
- that outside of his review of "internal documents," opinions about which should be excluded in general, Dr. Sirls lacks any reliable basis to offer opinions about the differences between laser-cut and mechanical-cut mesh devices, and in fact, was previously unaware of those differences; (*id.*, 68:20-24)
- that TVT and TVT-O devices can both rope, curl, and otherwise change shape if subject to improper tension; (*id.*, 70:2-8; 106:9-22; 107:19-108:7; 109:17-22)
- that mesh extrusion, exposure, and erosion into the vagina and other structures is unique to mesh; (*id.*, 89:21-24) and
- that in his practice, he has treated women with mesh implants who suffered recurrent or continued SUI, mesh exposure or erosion into the vagina, urethra and/or bladder; and has treated women who had to have their slings removed at least in part. (*Id.*, 116:21-118:5.)

His opinions must now be limited to the parameters of the above testimony.

#### IV. CONCLUSION

For reasons of the forgoing, the general opinions testimony of Dr. Sirs, as set forth herein, must be excluded as required by federal law.

Respectfully submitted,

Date: July 29, 2016

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**CERTIFICATE OF SERVICE**

I hereby certify that I filed the foregoing document on July 29, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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